K031045

JUL 10 2003

510K SUMMARY

The Aerolet Toiletlift is an ergonomically correct aid to daily living tool that replicates the natural sitting and standing process needed for an individual to void. When standing, the end-user leans slightly back onto the raised Aerolet toilet seat, pushes the down button with either hand and waits for the unit to safely bring them over the bowl at a controlled speed. It is adjustable to accommodate any height toilet and can be custom fitted to an individual or multiple user's height.

The Aerolet is also designed to allow the end user to stop on their way up or down allowing perineal cleaning.

Afterwards, the end-user pushes the up button to rise to return to a full standing position enabling the user to walk away without assistance. Those desiring less assistance can either manually decrease the lift at any point by letting off pressure to the up button. A switch can also be adjusted to decrease maximum lift height. The lift will stop at the preset limit and can not rise higher unless reset.

An optional wired remote hand control is also available. One side note, the remote hand control overrides the manual control built into the arm assembly. Other options include a variety of ergonomically correct seats from Pressalit. Soft seats are available in highly durable Gortex materials for durability.

The electronic components are manufactured specifically for the Aerolet by LINAK. Durable Rislan powder coating protects the steels from deterioration from the harsh bathroom environment and corrosive bodily fluids.

The mobile Aerolet is designed for the end user to take it with them when they travel or for use in institutional settings. The Bariatric version lifts consumers up to 880 pounds to enjoy the same benefits as that of the standard unit. This variation is accomplished by adding struts to the standard toiletlift. A larger seat adapts for larger users.

The AEROLET Toiletlift is the standard product comprised of components. It can also be reconfigured with other components to be used as a Shower lift by removing certain electronics out of the product and attaching the unit to the shower wall for stability.

All configurations of the AEROLET ToiletLift comply or exceed Manufacturer Guidelines for the United States of America and the European Union.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 2003

Ms. Stephanie W. Wolfkamp, RN
Economic Mobility, Incorporated
6785 Forest Oak Drive
Clemmons, North Carolina 27012

Re: K031045
Trade/Device Name: Aerolet ToiletLift, Model AER-01
Regulation Number: 21 CFR 890.3110
Regulation Name: Electric positioning chair
Regulatory Class: II
Product Code: INO
Dated: May 25, 2003
Received: June 2, 2003

Dear Ms. Wolfkamp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031045/A1

[redacted]

Economic Mobility, Inc
6785 Forest Oak Drive
Clemmons, North Carolina 27012 USA
800 342 8801
336 766 7686
www.toiletlift.com
info@toiletlift.com

Submitted by Stephanie Wolfkamp, RN

Indications for Usage

Aerolet ToiletLift "**K031045**" was developed to assist in patient ability to access bathroom facilities due to medical conditions such as the following:

Multiple Sclerosis
Muscular Dystrophy
Arthritis
Inclusion Body Myositis
Fredricks Ataxia
Parkinsons Syndrome
Post-Polio Syndrome
Fragile elderly
Rehabilitation
Leg fractures
Hip Replacement
Knee Replacement
Post-Operative Mobility

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number 031045

SK23